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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,634	12/05/2003	Peter M. Bonutti	2500 DIV 2 CON 2 DIV 3 CO	1118
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Kimberly V. Perry, Esq. U.S. Surgical, A Division of Tyco Healthcare Group, LP 150 Glover Avenue Norwalk, CT 06856				
EXAMINER				
WOO, JILLAN W				
ART UNIT		PAPER NUMBER		
3773				
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09/18/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/729,634

Applicant(s)

BONUTTI, PETER M.

Examiner

Julian W. Woo

Art Unit

3773

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/11/08.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4-9, 13 and 16-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-9, 13 and 16-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 4-9, 13, and 16-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. With respect to base claim 1, the specification does not describe a plurality of filaments permanently affixed to the cannula. That is, the extent of fixation of the filaments to the cannula is not specified.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 4, 8, 9, 13-17, 19, 20, 22-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Ginsburg (5,011,488). Ginsburg discloses, at least in figures 1-2B

and 5A-5E and col. 4, lines 50-60; col. 5 lines 3-30; col. 6, lines 6-17; and col. 6, line 61 to col. 7, line 15; a retractor including a flexible shaft (18) extending at least partially through a cannula (14); a plurality of filaments (32) extending from and affixed to the cannula, the plurality of filaments being repositionable from a first condition to a second condition; a sleeve (12) or sleeve member coaxially disposed about the periphery of and movable with respect to the cannula, the sleeve being axially movable between a first position blocking movement of the filaments radially outward and a second position in which the filaments are exposed to allow movement of the filaments radially outward; and a positioner (16 or 70) or inflatable positioner disposed at a distal end of the shaft, where the positioner is an inflatable bladder, where the cannula defines a passage therethrough which receives the shaft, where the plurality of filaments is disposed about the periphery of the positioner, where the positioner does not stretch when fully inflated, where the filaments are formed of an at least semi-rigid material, where the sleeve is formed of a flexible material, where the plurality of filaments is pivotally disposed at a distal end of the cannula or is pivotally connected to the shaft, where the distal positioning of the sleeve relative to the cannula repositions the plurality of filaments from the second condition to the first condition, where the proximal positioning of the sleeve relative to the cannula maintains the plurality of filaments in the first condition, where the plurality of filaments are parallel to one another in the first condition (see fig. 2C) and are radially spaced apart in the second condition (see fig. 2A), where the sleeve member is axially movable with respect to the shaft, where sleeve member is at least partially disposed about the plurality of filaments in the first position and disposed

proximally of the filaments in the second position, where sleeve member allows the plurality of filaments, where the sleeve member allows the plurality of filaments to transition from a first state to at least one subsequent state when the sleeve member is in a proximalmost position, where the sleeve member maintains the filaments in a first state when the sleeve member is in a proximalmost position, and where the plurality of filaments is parallel in the first state and extends radially outward in at least one subsequent state.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claims 5, 6, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ginsburg (5,011,488). Ginsburg discloses the invention substantially as claimed, but does not specifically disclose that the inflation bladder operates at inflation pressures from 10 mmHg to 1000 mmHG or from 100 mmHg to 1000 mmHg.

Nevertheless, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the inflation pressures as claimed, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges (of inflation pressure) involves only routine skill in the art.

Ginsburg also does not specifically disclose that inflation of the positioner repositions the plurality of filaments from the first condition to the second condition. Nevertheless, Ginsburg discloses, in col. 6, lines 15-17; that the positioner may conform to a conical geometry defined by the plurality of filaments. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made, to inflate the positioner to reposition the filaments from the first condition to the second condition (the abovementioned conical geometry) should the filaments be moved outside of the conical geometry by surrounding tissues. The inflation of the positioner and the movement of the filaments would ensure capturing and sealing of stenotic material within cannula 14.

7. Claims 7 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ginsburg (5,011,488) in view of Demeter (4,997,435). Ginsburg discloses the invention substantially as claimed, but does not disclose that the shaft is rigid and that the sleeve is formed of a rigid material. Demeter teaches, at least in col. 4, lines 42-47 and col. 5 lines 14-19, a device including a shaft (14) and a sleeve (11) that may be rigid or formed of a rigid material. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Demeter, to modify the shaft and sleeve of

Ginsburg, so that they are rigid or formed of a rigid material. Such modifications would allow Ginsburg's device to be easily inserted (without undue bending of the device) into non-tortuous hollow organs or readily-accessible surgical sites for the capturing and retrieval of unwanted matter from a patient's body.

Response to Amendment

8. Applicant's arguments with respect to claims 1, 4-9, 13, and 16-32 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773

September 19, 2008